

The provisionally elected claims of Group VI were formerly Claims 7, 10, 13, 16, 19, and 22 (now cancelled). The subject matter of the provisional election is now recited in new Claims 28-39.

REMARKS

In the first instance, Applicants through the undersigned, thank Examiner Collins and Examiner Nelson for providing helpful comments during a brief telephone interview held on Wednesday, February 26, 2003. Following the suggestions provided in the interview, Applicants have also submitted herewith a preliminary amendment, canceling Claims 1-22 and submitting new Claims 23-39.

The present invention is based on the discovery that modifying expression or activity of E2Fa or both E2Fa and DPa in a plant cell, results in a modulation of endoreduplication in the plant cell. Thus, the claims pending prior to preliminary amendment (now cancelled) as well as newly added Claims 23-39 are directed to a method for modulating endoreduplication in a plant or part thereof (Claims 23-26) as well as related compositions such as plant cells, plant parts, and plant materials (Claims 27-39). The method involves modifying expression or activity of: (i) E2Fa or (ii) E2Fa and DPa in plant cells, plant tissue, plant organs, or whole plants. *See* specification of the present application, page 11, second full paragraph. As described on page 14 of the specification, second full paragraph, different modes are available to modify expression or activity of E2Fa or both E2Fa and DPa in plant cells, plant tissue, plant organs, or whole plants. For example, overexpression, cosuppression, the use of ribozymes, anti-sense strategies, and gene silencing approaches may be used to modify expression or activity of E2Fa or E2Fa and DPa in plant cells.

DP is functionally related to E2F in the sense that DP is the dimerization partner of E2F. Thus, E2F and DP are attached to each other as an E2F-DP complex which acts as a transcription activator. When the level of E2F in the cell is modulated, the action/activity of the DP factor will automatically be influenced. In accordance with the invention, however, simultaneous modification of E2F and DP may be performed in order to reinforce the effects on endoreduplication accomplished by modulation expression or activity of E2F alone. Thus, modulation of endoreduplication may be accomplished by modifying expression or activity of *E2Fa*, or by modifying expression of *E2Fa* and *Dpa*. See specification, page 11, third full paragraph, and Example 16, last line.

As described in the specification of the present application (page 11, third full paragraph), there are available different *E2Fa* and *DPa* genes and their corresponding proteins for use in the methods and compositions of the presently claimed invention. For example, an *E2Fa* or *DPa* transgene may be used. As defined on page 20, final paragraph, of the specification, "transgene" refers to a nucleotide sequence which is heterologous (foreign) to any nucleotide sequence expressed by a cell or in a cell-free system. A transgene may also refer to a native gene that was isolated and reintroduced into the same organism." Claims 6 and 7 (now canceled) recite the term "transgene". Newly added claims 29-31 recite an *E2Fa* and/or *DPa* gene which is either native or heterologous to the plant cell.

Prior to the preliminary amendment submitted herewith, Claims 1-22 were present in this application and subjected to restriction by the Examiner under 35 U.S.C. §121 (37 C.F.R. §1.142) as follows:

Group I, Claims 1 and 3, drawn to a method for modulating endoreduplication in a plant by modifying expression or activity of *E2Fa*;

Group II, Claims 2 and 4, drawn to a method for modulating endoreduplication in a plant by modifying expression or activity of E2Fa and DP_a;

Group III, Claims 5, 8, 11, 14, 17 and 20, drawn to a plant cell which overexpresses a native E2Fa gene, a plant or part thereof comprising said plant cells, progeny and plant material;

Group IV, Claims 6, 9, 12, 15, 18, and 21, drawn to a transgenic plant cell comprising an E2Fa transgene, a plant or part thereof comprising said plant cells, progeny and plant material;

Group V, Claims 7, 10, 13, 16, 19 and 22, drawn to a plant cell which overexpresses a native E2Fa gene and a native DP_a gene, a plant or part thereof comprising said plant cells, progeny and plant material;

Group VI, Claims 7, 10, 13, 16, 19, and 22, drawn to a plant cell which overexpresses an E2Fa transgene and a DP_a transgene, a plant or part thereof comprising said plant cells, progeny and plant material;

Group VII, Claims 7, 10, 13, 16, 19, and 22, drawn to a plant cell which overexpresses an E2Fa transgene and a native DP_a gene, a plant or part thereof comprising said plant cells, progeny and plant material;

Group VIII, Claims 7, 10, 13, 16, 19 and 22, drawn to a plant cell which overexpresses a native E2Fa gene and a DP_a transgene, a plant or part thereof comprising said plant cells, progeny and plant material.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents distinct inventions.

As indicated, and in order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group VI, which group constituted Claims 7, 10, 13, 16, 19, and 22 prior to the preliminary amendment submitted

herewith, and reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application. The subject matter of the provisional election is now recited in new Claims 28-39.

However, pursuant to 37 C.F.R. § 1.111 and § 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof for the following reasons.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more *independent and distinct* inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.
35 U.S.C. 121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both *independent and distinct*, 37 C.F.R. §§1.141-142. Without independent and distinctness, a restriction requirement is unauthorized.

In the present application, neither the claims pending prior to preliminary amendment nor the newly added claims are "independent and distinct" so as to justify a restriction requirement. Newly added Claims 23 and 24 are directed to a method for modulating endoreduplication in a plant or plant part which comprise modifying expression or activity of either E2Fa or E2Fa and DPa. Claims 25 and 26 recite one mode of modifying expression or activity of either E2Fa or E2Fa and DPa; via overexpression of E2Fa or DPa. Claims 27 through 31 recite plant cells expressing or overexpressing products of native or heterologous *E2Fa* and *DPa* genes. Claim 32 recites a plant or plant part comprising the plant cells of Claims 27-31. Claim 33 recites a plant or plant part comprising the plant cells of Claims 27-31 and which also exhibits modulated endoreduplication. Claims 34 and 35 recite progeny of the plants of Claims

32 and 33. Claims 36 through 39 recite plant material obtained from the plants of Claims 32-33. Thus, the product Claims 27-39 cannot be considered "independent" of method Claims 23-26. Claims 23-39 are therefore very clearly interrelated and interdependent, not "independent and distinct."

The interdependence of the claimed method for modulating endoreduplication in a plant or part thereof, plant cells which overexpress a product of an E2Fa gene or an E2Fa and a DP α gene (whether native or heterologous to the plant cells), plants or parts thereof comprising the plant cells, and progeny or plant material of the plants, is confirmed --indeed, it is mandated-- by virtue of the fact that the description requirements of 35 U.S.C. §112 compel disclosure of all aspects of the invention in the one application which Applicants have filed. An application claiming a method of modulating endoreduplication in a plant by modifying expression or activity of E2Fa or E2Fa and DP α , (Claims 23-24) is required to disclose *inter alia*, how to make that invention. In other words, a description of the means for modifying expression of the E2Fa or E2Fa and DP α proteins such as e.g. overexpression (Claims 25-26) in plant cells (Claims 27-32) is a mandatory part of the application. Likewise, a patent application claiming plant cells, plants comprising such cells, progeny and plant material thereof which express or overexpress the product of an E2Fa gene or an E2Fa and DP α gene (Claims 27-39), is required to disclose *inter alia*, the use of such a product as in e.g., modulating endoreduplication (Claims 23-24). Indeed, if any of these aspects of a complete disclosure were omitted --perhaps by an applicant relying on what the Patent and Trademark Office considers "independent and distinct"-- the application could be considered defective under §112, first paragraph.

Consequently, it is clear that aspects of a given invention, such as a product, its use, and the process of producing that product, are necessarily interdependent, not independent, from each other.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or a compromise of the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal

challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 355, 228, U.S.P.Q. 837, 840 (Fed. Cir. 1986). In *Cierber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 436 (Fed. Cir. 1990), the Federal Circuit held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

The Examiner has justified the restriction requirement in this case in a number of ways: recital of applicable section of the Manual of Patent Examining Procedure (M.P.E.P. §§806.04, 808.01, and 806.05(f) and references to the different classes and subclasses of the

Patent and Trademark Office classification system in which the seven groups of claims would allegedly be classed. Neither basis justifies the restriction requirement in this application.

Reference to the Manual of Patent Examiner Procedure does not establish compliance with the narrow statutory authorization for restriction requirements. The Manual simply states the policy of the Patent and Trademark Office without force of law; it is not authority for expanding or altering a statutory grant of authority.

The PTO can prescribe requirements in the MPEP, providing those requirements are not inconsistent with the statute, the rules or the case law of the PTO's reviewing court.

In re Fressola, 22 U.S.P.Q.2d 1828, 1832 (Comm'r. PTO, 1992).

Reliance on the supposed classification of the groups of claims does not establish independent and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims he assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby

casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patent assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Hence, it is again respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all Claims 23-39 as added by preliminary amendment.

Respectfully submitted,

Ann R. Pokalsky
Ann R. Pokalsky
Reg. No. 34,697
Attorney for Applicant

DILWORTH & BARRESE
333 Earle Ovington Blvd.
Uniondale, NY 11553
(516) 228-8484
ARP bg

RECEIVED
MAR 11 2003
TECH CENTER 1600/2900